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APPLICATION NO.	FILING DATE	FIRST NAMED-INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,591	09/24/2003	Doug Duchon	57173/1481	5690
7590	09/12/2006			EXAMINER HUH, BENJAMIN
Kramer Levin Naftalis & Frankel LLP 919 Third Avenue New York, NY 10022			ART UNIT 3767	PAPER NUMBER

DATE MAILED: 09/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/669,591	DUCHON ET AL.
Examiner	Art Unit	
Benjamin Huh	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 03 July 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 23-27 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 23-27 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 6/5/06.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application
- 6) Other: _____.

DETAILED ACTION

Priority

The disclosure of the prior-filed application, Application No. 08/946293, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The claims of the instant application are not supported by the continuation in part of Application No. 08/946293 and therefore only obtain priority data back to the application of 08/957801 with a priority date of 10/24/1997.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 23-25 & 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Rosenberg et al (Us Patent No. 4596575) or Rubinstein (US Patent No. 3888239). Rosenberg et al and Rubinstein both disclose injection devices which automatically refill a syringe, the method comprising sensing a volume of fluid in a chamber of the syringe,

comparing said volume in said chamber with a preset amount of fluid necessary for a subsequent injection, retracting a plunger within said chamber of said syringe to a predetermined limit if the preset amount of fluid necessary for a subsequent injection is less than the volume of fluid sensed in said chamber, wherein predetermined limit maximally fills said chamber of said syringe, wherein the predetermined limit is less than a maximal volume of said chamber, with respect to Rosenberg see col. 1 line 60 – col. 2 line 5, col. 2 line 66 – col. 3 line 7, col. 5 line 65 – col. 6 line 17 and with regards to Rubinstein see col. 2 line 57 – col. 3 line 7 and col. 6 line 5 – 59.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg et al (Us Patent No. 4596575) or Rubinstein (US Patent No. 3888239) in view of Reinicke (US Patent No. 4684365). Even though Rosenberg or Rubinstein do not explicitly state the step of purging air from the chamber of the syringe attention is directed to Reinicke. The Reinicke reference teaches the step of purging air from the chamber of the syringe col. 7 line 47-51. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to incorporate the air purging step of

Reinicke into the method of Rosenberg or Rubinstein in order to provide a safer device and to allow for a faster refill.

Response to Arguments

Examiner would like to note that the method does not require the plunger to be retracted to a predetermined limit if the preset amount of fluid necessary for a subsequent injection is less than the volume of fluid sensed in the chamber, therefore the step does NOT have to occur if there is enough fluid left in the injector.

Applicant's arguments filed 6/12/06 have been fully considered but they are not persuasive.

Applicant argues that Rubinstein does not disclose comparing a volume in a chamber with a preset amount of fluid necessary for a subsequent injection and retracting a plunger within the chamber to a predetermined limit if the preset amount of fluid necessary for the subsequent injection is less than the volume of fluid sensed in the chamber, the examiner disagrees. The amount of fluid necessary for a subsequent injection for Rubinstein is deemed to be the full amount in order to ensure that there is enough fluid in the reservoir and therefore the plunger would retract when it realizes that the amount of volume is not full.

Applicant argues that Rosenberg does not teach or suggest all of the elements of claim 23 and more specifically that it fails with respect to the preset amount of fluid necessary for a subsequent injection, the examiner disagrees. In Rosenberg the term injection is utilized to portray the entire desired continuous injection of the pump of the

fluid to the subject during the time of the start of the injection til the time of the refill wherein the pump will eventually need to be refilled. Wherein the volume is also compared by the memory which stores the amount of fluid delivered thereby knowing the amount of drug left in the volume and the amount necessary to refill the volume for the next subsequent continuous injection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Brown et al (US Patent No. 4604093) also teaches the purging air step for refilling a syringe. Nowosielski (US Patent No. 6030359), Pokras (US Patent No. 5807340), and Kelly (US Patent No. 5743872) disclose refilling syringes to a preset amount and retracting the plunger to a predetermined limit.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Huh whose telephone number is 571-272-8208. The examiner can normally be reached on M-F: 9:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BHH
BHH

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

